

SECTION II **REMARKS**

Regarding the Amendments

Claims 1, 2, 11 and 13 have been amended as set forth in the above Complete Listing of the Claims. As amended, the claims are supported by the specification and the original claims. No new matter has been added, as defined by 35 U.S.C. § 132.

In view of the finality of the April 9, 2008 Office Action and to ensure substantive consideration of this response, a Request for Continued Examination is concurrently submitted herewith, together with payment of the appertaining RCE fees (see *infra*, “Fees Payable”).

Thus, upon entry of the amendments, claims 1-21 will be pending, of which claims 12-21 are withdrawn.

Withdrawn Rejection

Applicants gratefully acknowledge the withdrawal of the rejection of claims 1-11 under 35 U.S.C. § 112, second paragraph as indefinite.

Claim Rejections Under 35 U.S.C. § 112, 1st paragraph, enablement

In the Advisory Action mailed May 20, 2008 the examiner has maintained the rejection of claims 1-11 under 35 U.S.C. §112, first paragraph, as lacking enablement. Applicants respectfully disagree.

The examiner’s rejection is based on the alleged lack of enablement in the claimed transgenic rat. Specifically the examiner alleges that 1) the art of producing a transgenic animal with a given phenotype is unpredictable (Final Office Action, p. 3), and 2) the art suggests that a double transgenic comprising CD4 and CCR5 or CXCR4 does not represent a model for human HIV-1 infection as taught by Sawada et al. and Browning et al. (Final Office Action, p. 4).

The examiner’s attention is respectfully drawn to the amended claims set forth above. As amended, the claims do not recite the transgenic rat as a model for human HIV binding, but recite a transgenic rat that expresses at least a portion of a CD4 protein on PBMCs of the rat and where the expressed CD4 is capable of binding gp120. As such, the claimed transgenic rat has a predictable phenotype in the expression of CD4 on the surface of the PBMCs and the binding of

CD4 and gp120, when both are present. Such a rat may serve as a model for any situation where such binding is present.

It is respectfully submitted that the proper test for enablement is whether one so skilled in the art could reasonably make the transgenic rat that is taught in the specification without undue experimentation.

Clearly, the specification teaches one of skill in the art how to make a rat transgenic for HIV-1 (Examples 1-10), a rat transgenic for human CD4 (Example 11) and a double transgenic rat (Example 12). It is applicants' position that one of skill in the art could observe within each of such rats CD4 expressed on the surface of PBMCs, which is capable of binding to gp120.

As set forth in detail above, all aspects of pending claims 1-11 are enabled. Accordingly, withdrawal of the rejection of these claims under 35 U.S.C. §112, first paragraph, as lacking enablement is respectfully requested.

Claim Rejections Under 35 U.S.C. § 112, 1st paragraph, new matter

In the Advisory Action mailed May 20, 2008 the examiner has maintained the rejection of claims 1-11 under 35 U.S.C. §112, first paragraph, as containing subject matter that would be considered new matter with regard to the recitation "wherein the transgenic rat is a model for human HIV-1 binding" in claim 1 of the application.

The examiner's attention is respectfully drawn to Section I Amendments, beginning on page 3 above. As amended, claim 1 no longer contains the recitation on which the new matter rejection is based. Withdrawal of the rejection is therefore respectfully requested.

Fees Payable

The time for responding to the January 9, 2008 Final Office Action without extension was set at three months, or April 9, 2008. Applicants hereby request a 3 month extension of time under 37 C.F.R. § 1.136 to extend the deadline for response to and including July 9, 2008. Payment of the extension fee of \$525.00 specified in 37 C.F.R. § 1.17(a)(3), as applicable to small entity, is being paid by on-line credit card payment at the time of EFS submission of this Response.

The \$405.00 fee for a Request for Continued Examination specified in 37 C.F.R. § 1.17(e), as applicable to small entity, is also being paid by on-line credit card payment at the time of EFS submission of this Response.

The total fees submitted by on-line credit card payment at the time of EFS submission of this Response is therefore \$930.00 (\$525 + \$405).

Should any additional fees be required or an overpayment of fees made, please debit or credit our Deposit Account No. 08-3284, as necessary.

CONCLUSION

Based on the foregoing, all of Applicants' pending claims 1-11 are patentably distinguished over the art, and are in form and condition for allowance. The Examiner is requested to favorably consider the foregoing and to responsively issue a Notice of Allowance.

If any issues require further resolution, the Examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same.

Respectfully submitted,

Date: July 9, 2008

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<p>The USPTO is hereby authorized to charge any deficiency or credit any overpayment of fees properly payable for this document to Deposit Account No. 08-3284</p>
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